

*Sub B17*

1. An elongated device for treatment of thrombus or other unwanted material in a vessel or cavity of a living body comprising:

- a. a proximal end and a distal end;
- b. high pressure tubular means for conveying pressurized fluid from said proximal end to said distal end;
- c. pressurized fluid connection means for connecting the proximal end of said high pressure tubular means to a source of pressurized fluid;
- d. jet emanator means with at least one jet orifice for directing at least one high velocity fluid jet in the vicinity of said distal end, said jet emanator means being attached to and in fluid communication with said high pressure tubular means;
- e. second tubular means for conveying fluid, at least one of said jet orifices directing at least one high velocity fluid jet into said second tubular means;
- f. inflow means in said second tubular means, oriented so that at least one high velocity fluid jet entrains and draws surrounding blood or other fluid from a body vessel or cavity through said inflow means and into said second tubular means, and creating a region of elevated pressure in said second tubular means;
- g. outflow means in said second tubular means, located at said region of elevated pressure, said outflow means thereby providing for passage of fluid out from said second tubular means into a body vessel or cavity, creating one or more crossflow jets which provide force (normal and/or drag forces) which help to break thrombus or other unwanted material off the surface of a body vessel or cavity;

h. one or more of said high velocity jet(s) act to break apart thrombus or other unwanted material which has been entrained by said high velocity jet(s); and,

5 i. said high velocity jet(s), said inflow means, and said outflow means create a recirculation pattern so that fluid flows from said outflow means with radial flow vectors and circumferential and/or axial flow vectors to said inflow means and back into said second tubular means, thereby providing enhanced removal of thrombus or other unwanted material off the surface of a body vessel or cavity, and macerating the thrombus or other unwanted material by action of said high velocity jet(s).

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2. An elongated device for treatment of thrombus or other unwanted material in a vessel or cavity of a living body comprising:

- a. a proximal end and a distal end;
- b. high pressure tubular means for conveying pressurized fluid from said proximal end to said distal end;
- c. pressurized fluid connection means for connecting the proximal end of said high pressure tubular means to a source of pressurized fluid;
- d. jet emanator means with at least one jet orifice for directing at least one high velocity fluid jet in the vicinity of said distal end, said jet emanator means being attached to and in fluid communication with said high pressure tubular means;
- e. exhaust tubular means for conveying fluid from said distal end to said proximal end, at least one of said jet orifices directing at least one high velocity fluid jet into said exhaust tubular means, said exhaust tubular means providing for removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity;
- f. inflow means in said exhaust tubular means, oriented so that at least one high velocity fluid jet entrains and draws surrounding blood or other fluid from a body vessel or cavity through said inflow means and into said exhaust tubular means, and creating a region of elevated pressure in said exhaust tubular means;
- g. outflow means in said exhaust tubular means, located at said region of elevated pressure, said outflow means thereby providing for passage of fluid out from said exhaust tubular means into a body vessel or cavity, creating one or more crossflow jets which provide force

(normal and/or drag forces) which help to break thrombus or other unwanted material off the surface of a body vessel or cavity;

- h. one or more of said high velocity jet(s) act to break apart thrombus or other unwanted material which has been entrained by said high velocity jet(s); and,
- i. said high velocity jet(s), said inflow means, and said outflow means create a recirculation pattern so that fluid flows from said outflow means with radial flow vectors and circumferential and/or axial flow vectors to said inflow means and back into said exhaust tubular means, thereby providing enhanced removal of thrombus or other unwanted material off the surface of a body vessel or cavity, and macerating the thrombus or other unwanted material by action of said high velocity jet(s).

3. The device of claim 2, wherein said elevated pressure in said exhaust tubular means aids in driving fluid and thrombus or unwanted material debris from said distal end to said proximal end through said exhaust tubular means.

5 4. The device of claim 1, further comprising isolation means for isolating the portion of the body vessel or cavity near said distal end of said elongated device.

10 5. The device of claim 2, further comprising isolation means for isolating the portion of the body vessel or cavity near said distal end of said elongated device.

6. The device of claim 1 or 2, wherein high pressure fluid is provided in the range of approximately 150 to 500 psi.

7. The device of claim 1 or 2, wherein high pressure fluid is provided in the range of approximately 500 to 2500 psi.

15 8. The device of claim 1 or 2, wherein high pressure fluid is provided in the range of approximately 2500 to 50000 psi.

9. The device of claim 1 or 2, wherein high pressure fluid in said jet emanator means is in the range of 50 to 350 psi.

10. The device of claim 1 or 2, wherein high pressure fluid in said jet emanator means is in the range of 350 to 850 psi.

20 11. The device of claim 1 or 2, wherein high pressure fluid in said jet emanator means is in the range of 850 to 35000 psi.

12. The device of claim 1 or 2, wherein said high velocity jet(s) have maximum instantaneous centerline velocity of approximately 2,000 to 30,000 cm/s.

25 13. The device of claim 1 or 2, wherein said high velocity jet(s) have maximum instantaneous centerline velocity of approximately 7,000 to 20,000 cm/s.

14. The device of claim 1 or 2, further comprising another tubular means for passage of fluid or other material or for passage of devices such as guidewires, catheters, or imaging tools between said proximal end and said distal end.

5 15. The device of claim 1 or 2, further comprising pressurized fluid source means connectible to said pressurized fluid connection means, for providing pressurized fluid to said high pressure tubular means.

10 16. The device of claim 2, further comprising exhaust regulation means connected to said exhaust tubular means for regulation of the rate of removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity.

17. A method of macerating thrombus or other unwanted material in a body vessel or cavity, comprising the steps of:

5           a. inserting an elongated device having jet emanator means, inflow means, and outflow means into a body vessel or cavity, and advancing said elongated device to a site of thrombus or other unwanted material in the body vessel or cavity;

10           b. connecting said elongated device to a source of pressurized fluid so that fluid jet(s) emanate from said jet emanator means, entrains blood or other fluid which may contain thrombus or other unwanted material and draws the blood or other fluid into the elongated device through said inflow means, and creates a pressurized region in the elongated device which drives fluid and entrained blood or thrombus debris out of the elongated device through said outflow means creating crossflow jet(s); and,

15           c. using said elongated device to break apart thrombus or other unwanted material in the body vessel or cavity, where fluid forces from the crossflow jet(s) and a recirculation of fluid from said outflow means and back in through said inflow means and past said high velocity jet(s) macerates said thrombus or other unwanted material.

18. A method of removing thrombus or other unwanted material from a body vessel or cavity, comprising the steps of:

- a. inserting an elongated device having jet emanator means, inflow means, and outflow means into a body vessel or cavity, and advancing said elongated device to the site of the thrombus or other unwanted material in the body vessel or cavity;
- b. connecting said elongated device to a source of pressurized fluid so that fluid jet(s) emanate from said jet emanator means, entrains blood or other fluid which may contain thrombus or other unwanted material and draws the blood or other fluid into the elongated device through said inflow means, and creates a pressurized region in the elongated device which drives fluid and entrained blood or thrombus debris out of the elongated device through said outflow means creating crossflow jet(s);
- c. using said elongated device to break apart thrombus or other unwanted material in the body vessel or cavity, where fluid forces from the crossflow jet(s) and a recirculation of fluid from said outflow means and back in through said inflow means and past said high velocity jet(s) macerates said thrombus or other unwanted material; and,
- d. using said elongated device to remove thrombus or other unwanted material from the body.

19. A system for treatment of thrombus or other unwanted material in a vessel or cavity of a living body comprising:

- a. an elongated device having a proximal end and a distal end;
- b. high pressure tubular means forming part of said elongated device for conveying pressurized fluid from said proximal end to said distal end;
- c. pressurized fluid connection means located at said proximal end of said high pressure tubular means;
- d. pressurized fluid source means connected to said pressurized fluid connection means;
- e. jet emanator means with at least one jet orifice for directing at least one high velocity fluid jet in the vicinity of said distal end, said jet emanator means being attached to and in fluid communication with said high pressure tubular means;
- f. second tubular means forming part of said elongated device for conveying fluid, at least one of said jet orifices directing at least one high velocity fluid jet into said second tubular means;
- g. inflow means in said second tubular means, oriented so that at least one high velocity fluid jet entrains and draws surrounding blood or other fluid from a body vessel or cavity through said inflow means and into said second tubular means, and creating a region of elevated pressure in said second tubular means;
- h. outflow means in said second tubular means, located at said region of elevated pressure, said outflow means thereby providing for passage of fluid out from said second tubular means into a body vessel or cavity, creating one or more crossflow jets which provide force

(normal and/or drag forces) which help to break thrombus or other unwanted material off the surface of a body vessel or cavity;

- 5           i. one or more of said high velocity jet(s) act to break apart thrombus or other unwanted material which has been entrained by said high velocity jet(s); and,
- 10           j. said high velocity jet(s), said inflow means, and said outflow means create a recirculation pattern so that fluid flows from said outflow means with radial flow vectors and circumferential and/or axial flow vectors to said inflow means and back into said second tubular means, thereby providing enhanced removal of thrombus or other unwanted material off the surface of a body vessel or cavity, and macerating the thrombus or other unwanted material by action of said high velocity jet(s).

20. A system for treatment of thrombus or other unwanted material in a vessel or cavity of a living body comprising:

- a. an elongated device having a proximal end and a distal end;
- 5 b. high pressure tubular means forming part of said elongated device for conveying pressurized fluid from said proximal end to said distal end;
- c. pressurized fluid connection means located at said proximal end of said high pressure tubular means;
- 10 d. pressurized fluid source means connected to said pressurized fluid connection means;
- e. jet emanator means with at least one jet orifice for directing at least one high velocity fluid jet in the vicinity of said distal end, said jet emanator means being attached to and in fluid communication with said high pressure tubular means;
- 15 f. exhaust tubular means forming part of said elongated device for conveying fluid from said distal end to said proximal end, at least one of said jet orifices directing at least one high velocity fluid jet into said exhaust tubular means, said exhaust tubular means providing for removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity;
- 20 g. exhaust regulation means connected to said exhaust tubular means for regulation of the rate of removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity;
- 25 h. inflow means in said exhaust tubular means, oriented so that at least one high velocity fluid jet entrains and draws surrounding blood or other fluid from a body vessel or cavity through said inflow means and into said

exhaust tubular means, and creating a region of elevated pressure in said exhaust tubular means;

5           i. outflow means in said exhaust tubular means, located at said region of elevated pressure, said outflow means thereby providing for passage of fluid out from said exhaust tubular means into a body vessel or cavity, creating one or more crossflow jets which provide force (normal and/or drag forces) which help to break thrombus or other unwanted material off the surface of a body vessel or cavity;

10           j. one or more of said high velocity jet(s) act to break apart thrombus or other unwanted material which has been entrained by said high velocity jet(s); and,

15           k. said high velocity jet(s), said inflow means, and said outflow means create a recirculation pattern so that fluid flows from said outflow means with radial flow vectors and circumferential and/or axial flow vectors to said inflow means and back into said exhaust tubular means, thereby providing enhanced removal of thrombus or other unwanted material off the surface of a body vessel or cavity, and macerating the thrombus or other unwanted material by action of said high velocity jet(s).

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21. A catheter comprising:

- a. a first tube having a proximal end and a distal end;
- b. a second tube having a proximal end and a distal end, said first tube residing within and extending along the length of said second tube;
- c. a jet body at said distal end of said first tube, said jet body including a jet emanator;
- d. at least one outflow orifice and at least one inflow orifice formed in said second tube adjacent to said distal end thereof; and,
- e. said jet emanator having at least one jet orifice directed toward said outflow and inflow orifices.

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22. The catheter as defined in claim 21, wherein said at least one outflow orifice is located proximally of said at least one inflow orifice.

5 23. The catheter as defined in claim 21, wherein said at least one outflow orifice comprises a plurality of orifices and said at least one inflow orifice comprises a plurality of orifices.

24. The catheter as defined in claim 23, wherein all of said outflow orifices and all of said inflow orifices are positioned proximally of said at least one jet orifice.

10 25. The catheter as defined in claim 23, wherein all of said outflow orifices are located proximally of all of said inflow orifices.

26. The catheter as defined in claim 21, wherein said at least one jet orifice is located distally of said outflow and inflow orifices.

15 27. The catheter as defined in claim 21, wherein said at least one jet orifice is located proximally of said outflow and inflow orifices.

28. The catheter as defined in claim 21, wherein said at least one jet orifice comprises a plurality of jet orifices.

20 29. The catheter as defined in claim 21, wherein said jet emanator is in the form of a toroidal loop.

30. The catheter as defined in claim 21, wherein said jet emanator is in the form of a semi-toroidal loop.

25 31. The catheter as defined in claim 21, wherein said jet emanator is L-shaped.

32. The catheter as defined in claim 21, wherein said jet emanator is J-shaped.

33. The catheter as defined in claim 32, wherein said at least one jet orifice is located in the curved portion of said J-shaped jet emanator.

34. The catheter as defined in claim 32, wherein said at least one jet orifice is located at the extreme end of said J-shaped jet emanator.

5 35. The catheter as defined in claim 32, wherein the extreme end of said J-shaped jet emanator includes a necked-down portion and said at least one jet orifice is located at the tip of said necked-down portion.

10 36. The catheter as defined in claim 32, wherein said at least one jet orifice is defined by a tubular orifice member located at the extreme end of said J-shaped jet emanator.

15 37. The catheter as defined in claim 21, wherein said at least one outflow orifice and said at least one inflow orifice are defined by separate regions of a single orifice.

20 38. The catheter as defined in claim 21, further comprising a flexible tip assembly attached to said distal end of said second tube.

25 39. The catheter as defined in claim 38, wherein said flexible tip assembly comprises a tapered tube housing a radio-opaque marker.

40. The catheter as defined in claim 39, wherein said radio-opaque marker is a metal wire coil.

20 41. The catheter as defined in claim 40, wherein said metal wire coil has a closely wound portion and a loosely wound portion.

25 42. The catheter as defined in claim 21, wherein said jet emanator is located within said second tube at said distal end of said second tube.

43. The catheter as defined in claim 21, wherein said jet emanator is located outside of said second tube beyond said distal end of said second tube.

30 44. The catheter as defined in claim 21, wherein said second tube includes an exhaust lumen.

45. The catheter as defined in claim 21, wherein said proximal ends of said first and second tubes are connected to a manifold.